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APPLICATION FOR UNITED STATES LETTERS PATENT

for

MULTI-LUMEN MEDICAL ELECTRICAL LEAD BODY

by

Bret R. Shoberg
Jordon D. Honeck

ATTORNEY/AGENT OF RECORD:

Elisabeth L. Belden, Reg. No. 50,751
Medtronic, Inc.
710 Medtronic Parkway
Mailstop LC340
Minneapolis, Minnesota 55432
Telephone: (763) 514-4083
Facsimile: (763) 505-2530

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MULTI-LUMEN MEDICAL ELECTRICAL LEAD BODY

TECHNICAL FIELD

[0001] Embodiments of the present invention relate to medical electrical leads and more particularly to multi-lumen lead bodies.

BACKGROUND OF THE INVENTION

[0002] Implantable medical devices have long utilized medical electrical leads including elongated lead bodies, which carry one or more conductors coupling stimulation and or sensing electrodes or other types of sensors positioned at a target site to a connector coupled to a pulse generator or diagnostic device.

[0003] In order to carry out multiple functions, it is often desirable for a single lead body to carry multiple insulated conductors; however, it is also desirable for the lead body to have as small a profile or diameter as possible, to be flexible for implantation within a body, and to withstand damage under implant-environmental loading. These requirements may be addressed through the implementation of insulative multi-lumen tubing; embodiments presented herein exemplify novel configurations of multi-lumen tubing and arrangements of conductors therein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] The following drawings are illustrative of particular embodiments of the invention and therefore do not limit its scope, but are presented to assist in providing a proper understanding of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. The present invention will hereinafter be described in conjunction with the appended drawings, wherein like numerals denote like elements, and:

[0005] Figure 1A is plan view of a medical electrical lead according to one embodiment of the present invention;

[0006] Figure 1B is a partial plan view of an alternate distal end of the lead shown in Figure 1A;

[0007] Figure 2A is a section view through section line 2-2 shown in Figure 1;

[0008] Figure 2B is a section view of a lead body according to an alternate embodiment of the present invention;

[0009] Figure 3 is a section view of a multi-lumen tube according to an embodiment of the present invention; and

[0010] Figure 4 is a schematic section view of a multi-lumen tube according to an embodiment of the present invention.

DETAILED DESCRIPTION

[0011] The following description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides a convenient illustration for implementing exemplary embodiments of the invention.

[0012] Figure 1 is plan view of a medical electrical lead according to one embodiment of the present invention. Figure 1 illustrates a medical electrical lead 100 including a lead body 110, a tip electrode 118, a ring electrode 116, and two defibrillation electrodes 112, 114; lead body 110 carries at least four conductors (not shown; reference Figure 2A) to couple tip and ring electrodes 118 and 116 to a contact pin 126 and contact ring 127, respectively, of a connector leg 125 and defibrillation electrodes 112, 114 each to a contact pin 121 or 124 of a connector leg 122 or 123. Connector legs 122, 123, and 125, joined to lead body 110 via a trifurcation sleeve 120, are adapted to electrically couple lead 100 to a medical device and may each conform to an industry standard, for example DF-1 or IS-1, such as are known to those skilled in the art; configurations and constructions corresponding to connector legs 122, 123, and 125 are well known to those skilled in the art of lead construction.

[0013] According to embodiments of the present invention, lead body 110 comprises a multi-lumen tube composed of an elastomeric biocompatible and biostable insulative material, examples of which are well known to those skilled in the art and include silicone, polyurethane, and combinations thereof; one specific example of an appropriate insulative material is HP (high performance) silicone having a durometer between approximately 30 and approximately 70 on a shore A scale. Figure 2A is a section view

through section line 2-2 of Figure 1 showing an arrangement of lumens and conductors in a multi-lumen tube 20 of lead body 110 according to one embodiment of the present invention. Figure 2A illustrates tube 20 including a lumen 21 having an inner surface forming a substantially elliptical cross-section and a plurality of additional lumens 24A, 24B, 24C each having inner surfaces forming substantially circular cross-sections; cable conductors 12, 14, and 26 are shown positioned in lumens 24 and a coil conductor 28 positioned within lumen 21. Conductors include any suitable material known in the art of lead construction, for example an MP35N alloy, and are likewise formed according to methods known to those skilled in the art. Cable conductors 12, 14, and 26 may include insulative sheaths 27, as illustrated in Figure 2A, each having an outer diameter between approximately 0.005 inch and approximately 0.020 inch according to embodiments of the present invention.

[0014] Figure 2A further illustrates lead body 110 including an outer overlay sheath 25, which may be formed of a polymer such as polyurethane or silicone or a combination thereof; according to some embodiments of the present invention overlay sheath 25 is formed over multi-lumen tube 20 to make an outer diameter of lead body 110 approximately equal to that of electrodes coupled to lead body, e.g. electrodes 112, 114, and 116, illustrated in Figure 1A; furthermore, overlay sheath 25 may have a durometer greater than that of tube 20. According to alternate embodiments of the present invention, an overlay sheath is not included.

[0015] Referring back to Figure 1, according to one embodiment, cable conductors 12, 14, and 26 couple each defibrillation electrode 112, 114 to contact pin 121 or 124 and ring electrode 116 to contact ring 127, while coil conductor 28 couples tip electrode 118 to contact pin 126, wherein contact pin 126 may be rotated to extend and retract tip electrode 118 into and out from lead body 110 via coil 28 by means well known to those skilled in the art of lead construction. According to an alternate embodiment coil 28 need not rotate tip electrode 118 and a tip electrode coupled to coil 28 may take an alternate form as illustrated in Figure 1B. Figure 1B is a partial

plan view of an alternate distal end 101 of lead 100 including a tip electrode 102 and a tine structure 103 such as is commonly known to those skilled in the art.

[0016] Figure 2A further illustrates a sheath 29 surrounding coil conductor 28, which, according to one embodiment, serves as a lubricious liner between coil 28 and inner surface of lumen 21 to facilitate efficient torque transfer from contact pin 126 and tip electrode 118; coil 28 and sheath 29 fit within lumen 21 such that two separate spaces 22A and 22B having substantially crescent-shaped cross-sections are formed. In such an embodiment, sheath 29 may be formed of a fluoropolymer such as PTFE or ETFE. According to alternate embodiments, sheath 29 may only serve as redundant insulation for coil 28, not having lubricious properties, which are not required if coil is not used to extend and retract a distal tip electrode, for example electrode 102 illustrated in Figure 1B. In further alternate embodiments sheath 29 is not included and coil 28 alone fitted within lumen 21 may or may not have a sufficient diameter to form separate crescent-shaped spaces 22A and 22B; furthermore inner surface of lumen 21 may or may not have lubricious properties useful to facilitate extension and retraction of a tip electrode via coil 28. Coil 28 has an outer diameter between approximately 0.020 inch and approximately 0.040 inch and sheath 29 has an inner diameter between approximately 0.022 inch and approximately 0.042 inch and an outer diameter between approximately 0.026 inch and approximately 0.046 inch, according to embodiments of the present invention.

[0017] Additional alternate embodiments further include a fifth conductor 285 extending within a lumen 280 of coil 28, as is illustrated in Figure 2B; fifth conductor 285 is isolated from coil 28 by means of an insulative sheath 295 formed thereover. Fifth conductor 285 may be included in lead 110 to couple an additional electrode or physiological sensor to an additional contact on one of connector legs 122, 123, 125 or on an additional connector leg. It should be noted that conductors 12, 14, and 26, although illustrated having sheaths formed thereover, e.g. a sheath 27 illustrated in

Figure 2A, need not include such additional sheaths according to some embodiments of the present invention.

[0018] As illustrated in Figure 2A, according to one embodiment, an outer diameter of sheath 29 about coil 28 is approximately equal to or greater than a length of a minor axis of lumen 21, which is shown as item 32 in Figure 3. Figure 3 is a section view of multi-lumen tube 20 sans conductors. Figure 3 illustrates inner surface of lumen 21 forming a substantially elliptical cross-section including a major axis having a length 31, which is greater than minor axis length 32; length 31 ranges between approximately 0.025 inch and 0.080 inch and length 32 ranges between 0.015 inch and 0.065 inch, according to some embodiments. Lumen 21 is positioned with respect to lumens 24A-C such that a minimum wall thickness 30A, 30B for adequate insulation is maintained between each of lumens 21, 24A-C and minimum wall thickness 30A is maintained between lumens 21 and 24A-C and an outer surface 23 of tube 20; minimum wall thicknesses 30A-B range between approximately 0.002 inch and 0.015 inch according to embodiments of the present invention. Furthermore, according to embodiments of the present invention a minimum outer diameter of tube 20 is achieved while providing the adequate insulation via the arrangement of lumens 21 and 24A-C, which are sized to accommodate appropriate conductors (reference Figures 2A-C); a minimum outer diameter of tube 20 ranges between approximately 0.040 inch and approximately 0.120 inch and diameters of lumens 24A-C range between approximately 0.008 inch and approximately 0.025 inch according to some embodiments. Figure 3 further illustrates upper surfaces 21A and 21B of lumen 21 flattened, thereby creating asymmetrical portions on either side of the major axis, in order that minimum wall thickness 30B between lumens 24A and 24C and lumen 21 is maintained while maximizing space within lumen 21; such a configuration conforms herein to the term "substantially elliptical". In an alternate embodiment according to the present invention, lumen 21 is symmetrical about the major axis either being formed as an approximately 'pure' ellipse or having flattened

surfaces mirroring surfaces 21A-B, both configurations conforming to the term "substantially elliptical" used herein. Lengths 31 and 32 illustrated in Figure 3 generally correspond to relaxed dimensions or dimensions corresponding to lumen 21 in a relaxed state without a conductor disposed therein.

[0019] Figure 4 is a schematic section view of multi-lumen tube 20 illustrating forces, which may be applied for expansion and compression of lumen 21 to accommodate a conductor. According to some embodiments of the present invention, an outer diameter of a conductor, for example conductor 28 including sheath 29 illustrated in Figures 2A-B, is approximately equal to or greater than a height H, corresponding to length of minor axis 32 illustrated in Figure 3, therefore, to facilitate stringing of such a conductor into lumen 21 in a process of assembling a lead body, e.g. lead body 110, it may be necessary to expand height H of lumen 21. According to embodiments of the present invention the substantially elliptical cross-section formed by the inner surface of lumen 21 may be deformed from a relaxed state to increase height H. Figure 4 illustrates two means for deformation: a first comprising an external force F_e causing a compression C along the major axis leading to an expansion E along the minor axis and a second comprising an internal pressure increase resulting in internal forces F_i likewise leading to expansion E along the minor axis. Once a conductor having an approximately equal or larger outer diameter than height H is assembled into lumen 21, height H conforms to the outer diameter of the conductor while separate substantially crescent-shaped spaces, for example spaces 22A-B illustrated in Figure 2A, are maintained on either side of the conductor, for example conductor 28 including sheath 29 shown in Figure 2A.

[0020] In the foregoing specification, the invention has been described with reference to specific embodiments. However, it may be appreciated that various modifications and changes can be made without departing from the scope of the invention as set forth in the appended claims. For example, the cross-sections of the lumens and the number of lumens included in the

plurality of lumens illustrated herein as 24A-C may vary from that described. Furthermore, different types and numbers of conductors may be positioned within each of the lumens described herein without departing from the spirit of the present invention.